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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/813,214 | 03/29/2004 | Lasse Wesseltoft Mogensen | 8465/43 | 5131 |
| 7590 | 05/13/2008 | | | |
| Heidi A. Darc BRINKS HOFER GILSON & LIONE P.O. BOX 10395 CHICAGO, IL 60610 | | | EXAMINER MACNEILL, ELIZABETH | |
| | | | ART UNIT 3767 | PAPER NUMBER PAPER |
| | | | MAIL DATE 05/13/2008 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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| Office Action Summary | Application No. 10/813,214 | Applicant(s) MOGENSEN ET AL. |
| | Examiner ELIZABETH R. MACNEILL | Art Unit 3767 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 15 April 2008.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 50-100 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 60-64 is/are allowed.
- 6) Claim(s) 50-59, 65-72, 78-100 is/are rejected.
- 7) Claim(s) 73-77 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/96/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

Allowable Subject Matter

1. Claims 60-64 are allowed.
1. Claims 73-77 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 72, 78, 80-88, 90-100 are rejected under 35 U.S.C. 102(b) as being anticipated by Miskinyar (US 5,527,287).
Miskinyar teaches a sterile insertion set with housing (74) and cannula (22); a plunger (18); a lock (56); a spring (70); a forward end (62), a cover (72) covering an opening (60). As to claim 82-85, engagement areas on button (33); claim 86-88, back cover (38).
4. Claims 50-57, 59, 65-68, 72, 78-85, 89, 93-99 are rejected under 35 U.S.C. 102(e) as being anticipated by Safabash et al (US 6,293,925).

Safabash teaches an injector device with an infusion set having a housing (400) and a cannula (402) with tubing (412); a device housing (500), a cover (414), a plunger (504), a spring drive (507), lock (552), and manually deformable housing/trigger (508) to release the plunger. See Figs 35-40g. See adhesive (406). As to glucose sensor, see Col 1 line 30.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Safabash as applied to claims above, and further in view of Teeple, Jr (US 5,807,316). Safabash does not teach indicia relating to the shelf life of the device on the cover. As to claim 59, see Figs 40a-40d. Teeple teaches that it is known in the art to encode the shelf life of a device in a bar code on the device (Col 18 line 25).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the indicia of Teeple to avoid providing an expired device to the patient.

3. Claims 69-71, 86-88, 90-92 and 100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Safabash as applied above, and further in view of Miskinyar. Safabash does not teach a second cover on the back of the device or specify that the device is sterilized. Miskinyar teaches a needle holder with rigid upstanding cover (38)

and membrane cover (72). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the duplicate covers of Miskinyar in order to prevent accidental firing of the device and allow the device to be sterilized for the patient's use.

Response to Arguments

2. Applicant's arguments have been considered but are not persuasive. In response to applicant's argument that Miskinyar fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the insertion set is separable **while the cannula is disposed within the patient**) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

4. Regarding Safabash, the cover 414 is very clearly covering the entire needle at Fig 40b and can be used to sterilize the assembly. The cover of the applicant is also removed before placement.

Conclusion

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH R. MACNEILL whose telephone number is (571)272-9970. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth R MacNeill/
Examiner, Art Unit 3767

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/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767